UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS
	Hon. Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	

THE JOHNSON & JOHNSON DEFENDANTS'
REPLY MEMORANDUM IN SUPPORT OF THEIR MOTION
FOR SUMMARY JUDGMENT AS TO CLASS 1 AND CLASS 2

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PRELIMINARY STATEMENT

Plaintiffs' opposition confirms that Procrit and Remicade should be dismissed from the case. The spreads on these two medicines are too minimal to be actionable under plaintiffs' only remaining theory of liability. There is no evidence that a single class member was deceived by the spreads on these products.

During the class certification hearing the Court asked J&J's counsel why drugs like Procrit and Remicade could not simply be "thrown out" of the case, thereby limiting the case to drugs "where there's a dramatic spread?" The answer, of course, is that the Court can and should dispose of drugs with minimal spreads. J&J's motion for summary judgment should be granted.

ARGUMENT

I. THE UNDISPUTED MATERIAL FACTS REGARDING PROCRIT AND REMICADE ENTITLE THE J&J DEFENDANTS TO SUMMARY JUDGMENT

A. Plaintiffs' Abandonment of the "AWP = ASP" Theory Requires Summary Judgment

As we predicted in our opening brief (pp. 2-3), plaintiffs have jettisoned the theory that, for Class 1 and Class 2, AWP is supposed to equal ASP "by regulation" or "by statute." Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment ("Hartman Opp. Decl."), ¶ 5 ("**I have never taken the position** that Defendants should have **set the 'AWP equal to the ASP**.'") (original emphasis). Instead, plaintiffs now maintain that a drug's AWP must fall "within some *reasonable zone* of actual averages." *See* Plaintiffs' Memorandum in Opposition to Track 1 Defendants' Joint Motion for Summary Judgment ("Pl. Opp. Memo.") at 6 (emphasis added). They agree that there is no liability if the AWP is "*rationally linked* to actual costs." *Id.* at 5 (emphasis added).

This change in theory sounds the death knell for plaintiffs' case against the J&J Defendants. It cannot be disputed that the spreads on Procrit and Remicade fall within a "reasonable zone of actual averages." Nor can it be disputed that their AWPs are "rationally linked to actual costs." Accordingly, there is no liability.

B. The Spreads on Remicade and Procrit Are Not Unlawful Under Plaintiffs' Only Remaining Theory of Liability

The spreads on Procrit and Remicade were minimal. According to Dr. Hartman, between 1991 and 2003, only 16 out of 116 Procrit NDCs had spreads in excess of 30%, and eight of those 16 were between 30% and 33%. (Dr. Hartman originally said that a 33% spread was not fraudulent but changed his mind after he calculated the J&J spreads.) According to J&J's expert, Mr. Dukes, only one out of 116 exceeded 30%. Likewise, for Remicade, Dr. Hartman says that the spreads ranged from 30.8% to 36.1%. According to Mr. Dukes, they never exceeded 30%.

Modest spreads of this magnitude are not "mega-spreads."[1] To the contrary, they are well within the range of spreads known to the government and documented in a host of government surveys and reports, including two surveys that looked specifically at Procrit. Thus, even if Dr. Hartman's numbers are assumed to be correct (which the Court should not assume, *see* Point II, *infra*), the spreads on Procrit and Remicade are not actionable.

The government issued numerous reports during the class period documenting spreads much larger than those calculated by Dr. Hartman and Mr. Dukes for Procrit and Remicade. *See, e.g.*, Exhibits to Declaration of Lucy Fowler (Mar. 15, 2006):

- Ex. 13, Senate Report: "the [Veteran's Administration] achieves an average discount of 41% off [AWP] for single source drugs and 67% off the published

[1] In his recent declaration, Dr. Hartman states that "[r]elative to ASP, 1900% is a mega-spread; relative to AWP, 95% is a mega-spread." Hartman Opp. Decl., ¶ 24.e.

AWP for multiple source drugs … [and] hospitals, HMOs and nursing homes that contract with wholesalers achieve discounts up to 99% off AWP";

- Ex. 25, GAO Report: "The discounts for the drugs in our study ranged from 2 percent to 99 percent below AWP";
- Ex. 26, HHS-OIG Report: physician discounts ranging from 9% to 83% below AWP;
- Ex. 42, House Comm. Report: "Medicare reimbursement for the top 10 oncology drugs ranges from 20% to nearly 1000% more than acquisition cost."
- Ex. 46, HHS-OIG Report: "[W]e've identified Medicare allowances that were 11 to 900 percent greater than the drug prices available to the physician and supplier communities."
- Ex. 54, HHS Report: "On average, for the 22 drugs in the OIG study, Medicare payment at the AWP allowed a markup of 41 percent above the drug's wholesale catalogue price advertised to the physicians and suppliers who bill Medicare."
- Ex. 67, GAO Report: "For most physician-administered drugs, the average discount from AWP ranged from 13 to 34 percent; two physician administered drugs had discounts of 65 percent and 86 percent."

These reports show, beyond question, that the government knew about spreads well in excess of 30%.

1. Remicade

Dr. Hartman surmises that payors were deceived by "hidden," "secret" or "unexpected" discounts below the published list price and AWP, creating the "mega-spreads" about which plaintiffs complain. This theory has no application to Remicade because Centocor did not offer discounts and rebates to physicians. In fact, the *published*, *i.e.*, not "hidden," difference between Remicade's list price and AWP was 30%.

If, as Dr. Hartman suggests, payors paid close attention to the published list price because they expected it to exceed provider acquisition cost by some "reasonably predictable" amount, then, in the case of Remicade, they could not have been deceived. In fact, Dr. Hartman's own

calculations demonstrate that payors could not have been deceived. He finds (albeit incorrectly, *see* Point II, *infra*) that Remicade's "real" or "revealed" spread exceeded the published spread by 0.8% to 6.1.%, apparently relying government discounts and small services fees earned by specialty distributors. Declaration of Jayson S. Dukes, Mar. 15, 2006 ("Dukes Decl."), ¶¶ 49, 52. Minimal variations from the published spread of 0.8% to 6.1% could not have resulted in deception. Using plaintiffs' phrase, Remicade's published list prices fell within "some *reasonable zone* of actual average prices." Accordingly, there is no liability.

2. Procrit

According to Dr. Hartman, between 1991 and 2003, only 16 out of 116 Procrit NDCs exceeded 30%, and eight of those 16 were between 30% and 33%. Thus, as in the case of Remicade, Procrit's AWP was "rationally linked to actual costs."

The government surveys upon which Dr. Hartman relies found some spreads within his yardstick and other spreads outside his yardstick. *See* Hartman Opp. Decl., ¶ 11.b. and d. In fact, the government surveys of Procrit's spread found it to be *within* Dr. Hartman's yardstick.

Procrit's spread was measured in two separate government surveys. In the first survey, which was conducted in 1995 and 1996, the Office of Inspector General compared wholesale catalogue prices to AWP for 22 Part B drugs, including Procrit. Reply Declaration of Andrew D. Schau, April 28, 2006 ("Schau Reply Decl."), Exh. B. The OIG determined that the *average* difference between the listed catalogue price and AWP was 35% in 1995 and 29% in 1996. The spread between the catalogue price and AWP on one drug exceeded 90%. Procrit's spread was among the smallest in the survey – 17% in 1995, and 13% in 1996. *Id.* at App. C-2 and C-3.[2]

[2] The Procrit spreads listed in Dr. Hartman's report are larger than those listed in the OIG report because Dr. Hartman compares AWP to average selling price, whereas the OIG compared AWP to wholesale (footnote continued)

The range of spreads that Dr. Hartman calculates on Procrit is *identical* to the *average* spreads listed in the OIG report – 29% to 35%. *Compare id.* at App. C-2 and C-3 *with* Dukes Decl., Exh. 6. Notably, Dr. Hartman's 30% liability yardstick is actually *below* the average spread identified in the 1995 survey, and only slightly above the average spread identified in 1996. This means that plaintiffs have set their liability threshold so low that it imposes liability on drugs with "average" spreads, even when the average is calculated using wholesale catalogue prices that do not include discounts and rebates.[3]

A subsequent report published by the Government Accounting Office in 2001 confirms that the government remained knowledgeable about Procrit's acquisition price and spread. The survey compared AWP to the discounted prices available to "low volume" purchasing physicians and to the prices available from wholesalers (referred to as the "widely available price"). The study examined the pricing on 16 Part B drugs, including Procrit. Schau Reply Decl., Exh. C.

The GAO survey revealed that Procrit could be purchased by physicians at an average discounted price of 22.1% below AWP. This discount is equivalent to a spread of 28.4% above ASP. The GAO found that the *average* discount below AWP was 29.6%, which is equivalent to a spread of 42.0% above ASP. The discounts identified by the GAO, and the corresponding spreads, are summarized in the following table (Schau Decl., Exh. C at Table 5):

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catalogue prices. Catalogue prices are higher than average selling prices because they do not include discounts and rebates paid to providers. As a result, there is less of a difference between AWP and the catalogue price than there is between AWP and ASP.

[3] This is a clear departure from what plaintiffs have been telling the Court from the outset. *See, e.g.*, Written Tutorial of Meredith Rosenthal, Ph.D.," pp. 2-3 ("There are approximately 65,000 different prescription drugs in the United States market. The use of AWP as a pricing mechanism for the vast majority of these drugs is not at issue in the AMCC or in this motion. The plaintiffs instead claim that with respect to 132 of the drugs manufactured by the five fast track defendants (a subset of all drugs manufactured by these companies) the use of AWP as an industry standard was exploited by defendants…." (footnotes omitted)).

Discounts Available to Low Volume Physician Purchasers
Based on 2001 GAO Report

Drug	Discount Below AWP	Spread Above Selling Price
Leuprolide acetate (for depot suspension)	32.8%	48.8%
Rituximab	15.7%	18.6%
Goserelin acetate implant	22.3%	28.7%
Docetaxel	22.0%	28.2%
Filgrastim (480 mg)	22.4%	28.9%
Pamidronate disodium	18.0%	22.0%
Filgrastim (300 mg)	21.7%	27.7%
Paclitaxel	25.8%	34.8%
Irinotecan	27.1%	37.2%
Carboplatin	20.0%	25.0%
Gemcitabine HCl	16.1%	19.2%
Dolasetron mesylate, injection	62.0%	163.2%
Granisetron HCl, injection	28.1%	39.1%
Leucovorin calcium	90.4%	941.7%
Epoetin alfa for non-ESRD use	22.1%	28.4%
Ondansetron HCl, injection	26.4%	35.9%
Average:	29.6%	42.0%

This demonstrates that the government knew that the *average* discount available to physicians on all 16 drugs produced a spread of 42%, well above the 28.4% spread reported for Procrit. Notably, more than half of the drugs surveyed had spreads that exceeded the spread on Procrit, including two with spreads of 163.2% and 941.7%. It is thus clear the government knew that physician spreads in excess of Procrit's spreads – and in excess of Dr. Hartman's liability threshold – were the norm, not the exception.

This knowledge did not prompt Congress to change the level of reimbursement. In fact, as set forth in the Track 1 Defendants' joint memoranda, when HCFA tried to reduce reimbursement, 89 members of Congress intervened to prevent the proposed changes. Track 1 Memo. at 8. Their concern was that cuts in reimbursement would mean that "many physicians

will be unable to continue providing cancer care in their offices, and patients will be deprived of a humane, convenient and cost-effective treatment option." *Id.* In November 2000, Congress barred HCFA from "directly or indirectly decreas[ing] the rates of reimbursement for drugs covered under Part B until the Comptroller General (*i.e.*, the GAO) studied the issue of Medicare drug reimbursement." *Id.*

II. PLAINTIFFS HAVE FAILED TO SUBMIT EVIDENCE SUFFICIENT TO DEFEAT SUMMARY JUDGMENT ON J&J'S SPREAD CALCULATIONS, WHICH SHOW THAT THE SPREADS ON REMICADE AND PROCRIT DID NOT EXCEED 30 PERCENT

The Track 1 Defendants' joint briefs demonstrate that Congress and CMS never intended to subject Part B drugs to a 30% liability yardstick. But even if the Court were to adopt Dr. Hartman's yardstick, summary judgment would still be required as to Remicade and Procrit.

The Court has before it two sets of spread calculations, one by Dr. Hartman, and the other by Mr. Dukes. As noted above, Mr. Dukes found that the Remicade and Procrit spreads are 30% or less, and, as such, do not exceed Dr. Hartman's 30% liability threshold. Dr. Hartman says that the spreads are slightly higher.[4]

Plaintiffs argue that this amounts to a "battle of the experts" which creates a triable issue of fact. Pl. Opp. Memo. at 13-15. In truth, there is no battle of the experts here. Mr. Dukes does not base his calculations on a competing methodology. He applied Dr. Hartman's methodology. The only issue is whether, in applying Dr. Hartman's methodology, his calculations, or Dr. Hartman's, are correct.

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[4] Hartman initially reported three anomalous spreads on Procrit that were greater than 50%, including one that was 221.3%. Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages (Dec. 15, 2005) ("Hartman Liability Report"), Attachment G.4.c. These anomalous spreads do not appear in Dr. Hartman's Supplemental Report. *See* Supplemental Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages ("Hartman Supplemental Report") dated February 3, 2006, Attachment G.4.c.

This question has a readily attainable, objective answer which is not subject to genuine dispute. In fact, plaintiffs already have all the information they need in order to determine which set of numbers is correct.

The issue is straightforward. As Dr. Hartman admits, in order to apply his methodology correctly, one must comb through the J&J Defendants' voluminous data files and identify and remove all sales transactions involving "hospitals, government entities, managed care dispensaries, and those units distributed through wholesalers which are not later distributed to the physicians who in turn administer to the Class…." Hartman Liability Report, ¶ 61. Mr. Dukes discovered and removed more transactions that, according to Dr. Hartman's criteria, should have been removed. Dukes Decl., ¶ 49.

Mr. Dukes has provided plaintiffs with a comprehensive listing of each transaction that he excluded from his calculations. *Id.* at ¶ 48, Exhs. 1 and 2. Mr. Dukes has also provided a listing of the transactions that he believes Dr. Hartman's staff should have excluded, but failed to exclude. *Id.* at 49, Exhs. 14 and 15. In responding to J&J's motion, all Dr. Hartman needed to do in order to confirm whether Mr. Dukes' calculations are correct was to examine these lists to see if he agrees or disagrees that the listed transactions should have been excluded.

Plaintiffs' response does not create an issue of fact. Dr. Hartman has made no attempt to confirm or refute Mr. Dukes' calculations. He contends that Mr. Dukes was given "more and better data" than he was, and that he did not receive all of the information he asked for during discovery. Hartman Opp. Decl., ¶ 25.a. As a consequence, Dr. Hartman says he "cannot offer an opinion concerning the correctness or incorrectness of [Mr. Dukes'] assertions regarding the J&J data." *Id.*, ¶ 25a.

Dr. Hartman's complaints are unfounded. Mr. Dukes and Dr. Hartman received exactly the same data. Schau Reply Decl., ¶ 8. Moreover, plaintiffs never complained that the data produced to them during the discovery period was deficient. Nor did plaintiffs lack the opportunity to ask questions about the data. In fact, J&J's employees were interviewed by Dr. Hartman's staff, and they answered all of their questions. Plaintiffs had ample opportunity to obtain the information they needed during the discovery period. *Id.*, ¶¶ 9-10.[5]

Plaintiffs' utter failure to respond to Mr. Dukes' critique of Dr. Hartman's calculations is legally insufficient to defeat summary judgment. In order to defeat summary judgment, a party must point to "specific facts demonstrating that there is, indeed, a trial worthy issue." *Nation Nat'l Amusements, Inc. v. Town of Dedham*, 43 F.3d 731, 735 (1st Cir. 1995), *cert. denied*, 515 U.S. 1103 (1995); *see also Bryant v. Caritas Norwood Hosp.*, 345 F. Supp. 2d 155, 162 (D. Mass. 2004) (in determining whether a nonmovant meets this burden, "[a] genuine dispute of material fact cannot be established through 'conclusory allegations, improbable inferences, and unsupported speculation' alone," quoting *Medina-Munoz v. R.J. Reynolds Tobacco Co.*, 896 F.2d 5, 8 (1st Cir. 1990)).

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[5] Because plaintiffs cannot show that they lacked the opportunity to pursue the discovery they needed during the discovery period, their request under Rule 56(f) for more discovery and a stay of summary judgment should be denied. *See Majewski v. Automatic Data Processing, Inc.*, 274 F.3d 1106, 1114 (6th Cir. 2001) ("Where the full period for pretrial discovery has run its course, a party should generally be precluded from reopening discovery months after it has closed in a last-ditch attempt to salvage a deficient claim or defense."); *Jocham v. Tuscola County*, 239 F. Supp.2d 714, 734 (E.D. Mich. 2003) ("Rule 56(f) may be invoked only when the plaintiff has been unable to acquire needed discovery through due diligence, not to permit further discovery when the plaintiff had failed to thoroughly examine her opportunities in the time available to her."); *McNerney v. Archer Daniels Midland Co.*, 164 F.R.D. 584, 588 (W.D.N.Y. 1995) (denying 56(f) request because "[a]pplications to extend the discovery deadline must be made prior to expiration of the deadline…. Rule 56(f) is not intended to circumvent discovery orders."); *Carlton v. Interfaith Medical Center*, 612 F. Supp. 118 (E.D.N.Y. 1985) (plaintiff's claim of inadequate discovery would not be considered on defendant's summary judgment motion where plaintiff had ample time to complete discovery before the cut-off and made no showing of good cause for failing to do so).

Conclusory opinions from an expert are insufficient to create a triable issue of fact. For example, in *Hayes v. Douglas Dynamics, Inc.*, 8 F.3d 88, 92 (1st Cir. 1993) the First Circuit upheld entry of summary judgment in a wrongful death case where plaintiffs' expert did not "include the factual basis and the process of reasoning" necessary to determine whether his conclusions were viable. The Court noted that it would not "allow the reliance on a bare ultimate expert conclusion to become a free pass to trial every time that a conflict of fact is based on expert testimony." *Id.*

Dr. Hartman's declarations are chocked full of charts, footnotes, equations, and all sorts of scientific-sounding jargon. *But with respect to his calculations of the Procrit and Remicade spreads, Dr. Hartman's declarations are entirely conclusory.* Dr. Hartman identifies the formula he used to make his calculations, and he provides his ultimate conclusions, but he does not provide any information about the calculations themselves. Unlike Mr. Dukes, Dr. Hartman does not identify any of the transactions that were excluded from his calculations. Thus, his conclusions about the Procrit and Remicade spreads are the sort of "bare ultimate expert conclusions" that the First Circuit has said are insufficient to defeat summary judgment.

Plaintiffs have not identified any specific facts that would permit the Court to conclude that Mr. Dukes' calculations are subject to genuine dispute. As a consequence, they have failed to dispute that the spreads on Procrit and Remicade did not exceed Dr. Hartman's 30% liability threshold.

III. PLAINTIFFS CANNOT AVOID SUMMARY JUDGMENT BY DISTORTING THE RECORD AS TO THE J&J DEFENDANTS' CONDUCT

A. Centocor's Marketing of Remicade Was Not Improper

Plaintiffs cannot salvage their case against Remicade by complaining about Centocor's allegedly improper marketing practices. They fault Centocor for "develop[ing] a computer

program to use with payors which revealed only the AWP and nothing else." Pl. Opp. Memo. at 7. They note that a Centocor employee, Laura Glassco, testified that she did not discuss physician acquisition cost when she made presentations to insurers. *Id.* They conclude from this that Centocor made a "systematic effort to avoid revealing spreads and acquisition costs to insurers." *Id.*

This is nonsense. From a payor's perspective, the relevant "cost" figure was the cost of reimbursement, *i.e.*, how much the health plan would have to pay in order to compensate the physician for purchasing and administering Remicade. Moreover, as noted above, payors had ready access to Remicade's published list price. There were no discounts to physicians below the list price, so there was no reason to elaborate.

The computer program referenced in plaintiffs' opposition papers was one of the tools Centocor used with payors to demonstrate that Remicade's reimbursement cost was *lower* than for other drugs. Plaintiffs' JJ Ex. 9. The program shows, based on Remicade's AWP and other factors, that the "Annual Cost to health plans" of reimbursing for Remicade was less than the cost of reimbursing Enbrel, a competing drug. In particular, the program enabled the health plan to calculate the "Annual Per Person Savings (Cost) with Remicade" and the "Annual Savings (Cost) per 1000 patients treated." In short, the program showed payors that Remicade could save payors money.

B. Ortho Biotech Did Not Hide Procrit's Acquisition Cost From the Government

The OIG and GAO surveys prove beyond question that the government was aware of Procrit's acquisition cost and the size of its spread. Nevertheless, plaintiffs argue that the government was "unaware of Procrit's actual acquisition cost." Pl. Opp. Memo. at 3. Plaintiffs do not base this statement on government sources, for obvious reasons. Rather, they cite memos

written in 1996 and 1997 by Cathleen Dooley, an employee in Ortho Biotech's office of legislative affairs. *Id.* at 3-7. Ms. Dooley's memos do not support plaintiffs' claim that the government was deceived.

Ms. Dooley's memos addressed the possibility that a government survey of Procrit's acquisition cost could lead to a reduction in the reimbursement rate. Ortho Biotech does not dispute this point – the Medicare statute required it. At the time, Medicare reimbursement was the lesser of "estimated acquisition cost" or AWP. HCFA initiated surveys in 1994 to determine EACs for all Part B drugs but abandoned the effort at the direction of the Office of Management and Budget. As a result, EACs were never established, and HCFA continued to reimburse based on AWP.

It is no secret that AWP was higher than EAC. Thus, completion of a HCFA survey would necessarily have resulted in reduced reimbursement for Procrit and every other Part B drug. In fact, Ms. Dooley testified that HCFA "expected" that the surveys would show that physicians were paying less than AWP. Schau Reply Decl., Exh. D (Dooley Dep. at 415-17). Yet Ortho Biotech did nothing to stop the government from conducting surveys of Procrit's acquisition price. *Id.* (Dooley Dep. at 605-06.) In fact, as discussed above, unrelated to EAC, the OIG and the GAO did survey Procrit's acquisition price.

IV. THE CLAIMS BY MR. & MRS. SHEPLEY RELATING TO PROCRIT MUST BE DISMISSED

Mr. Shepley's medical records indicate that he was administered Amgen's "EPOGEN 1000U," for which he was "charged" $780. Mr. Shepley's records make no reference to Procrit, merely to a billing code (Q0136) for epoetin alfa. This billing code can refer to Epogen or Procrit. *See* Pl. Resp. to J&J Rule 56.1 Statement, ¶ 3. Accordingly, there is no evidence that Mr. Shepley received Procrit.

Plaintiffs say they asked the clinic where Mr. Shepley was treated for an affidavit stating that he was administered Procrit, but were prevented by the clinic's attorney. Pl. Opp. Memo. at 17, n.12. As a result, plaintiffs rely on a hearsay letter drafted by plaintiffs' counsel. They ask the Court to accept this hearsay evidence because someone from the clinic might "potentially [be] able to testify at trial." *Id.* at 16.

Local Rule 56.1 provides that facts are deemed admitted unless contradicted by admissible evidence. It is settled law in this Circuit that hearsay may not be used to defeat summary judgment. *See Garside v. Osco Drug, Inc.*, 895 F.2d 46, 50 (1st Cir. 1990) ("Hearsay evidence, inadmissible at trial, cannot be considered on a motion for summary judgment."); *Copy Cop, Inc. v. Trask Printing, Inc.*, 908 F. Supp. 37, 41-42 (D. Mass. 1995) (Saris, J.) (ruling that "[hearsay] evidence would not be admissible at trial and thus cannot be considered in a motion for summary judgment.")

Plaintiffs do not seriously contest the fact that neither the clinic's $780 "charge" nor Mr. Shepley's $132.60 payment appears to have anything to do with Procrit's AWP. Their sole argument is that Mr. Shepley was treated for prostate cancer and "the Medicare allowable for such treatment is based on AWP." Pl. Opp. Memo. at 17. From this they conclude that "Mr. Shepley's co-payment must also be based on AWP." *Id.*

This reasoning is circular. It is undisputed that Mr. Shepley was charged $780, and paid $132.60. It is also undisputed that neither amount bears any discernable relationship to Procrit's AWP. That other prostrate cancer patients receiving epoetin alfa may be billed on the basis of AWP is irrelevant to Mr. Shepley's particular claim.

Lastly, Mr. Shepley does not state a claim under Nevada law because he never saw, read, or received the challenged statement. In *Scaffidi v. United Nissan*, No. CV-S-04-1366, 2005 WL

3737892, *7 (D. Nev. Dec. 30, 2005), the court granted summary judgment under NEV. REV. STAT. § 41.600 because "[t]here is no evidence that at any time [defendant] made a false statement to, or for that matter communicated with, [plaintiff] in the course of its business." Plaintiffs argue that *Scaffidi* is distinguishable because the defendant in that case "had done nothing intentional to deceive the plaintiff." Pl. Opp. Memo. at 20. The same is true here.

V. THE CLAIMS BY MRS. YOUNG'S HUSBAND RELATING TO REMICADE MUST BE DISMISSED

Mrs. Young never received a bill for Remicade. Her therapy was covered by supplemental insurance. Her sole financial obligation to the clinic where she was treated was to pay a fixed $1,190 deductible. Schau Reply Decl, Exh. A, Statements 9-11.

Nevertheless, plaintiffs argue that Mrs. Young paid for Remicade based on Remicade's AWP. This argument overlooks the fact that she paid a fixed deductible that covered her entire course of therapy, not just Remicade. *See* Pl. Opp. Memo. at 21 ("the Youngs paid this *and other inflated charges* up to the limit of their deductible") (emphasis added). There is no evidence that Mrs. Young's deductible amount was related to Remicade's AWP, *i.e.*, there is no evidence that her payment obligation would have been different if Remicade's AWP had been different.

The claim is also deficient because Oklahoma's consumer protection law exempts "[a]ctions or transactions regulated under laws administered by . . . any . . . regulatory body or officer acting under statutory authority of . . . the United States." 15 OKLA. STAT. tit. 15, § 754 (emphasis added); *Patterson v. Beall*, 19 P.3d 839, 847 n.13 (Okla. 2000). It is undisputed that transactions under Medicare Part B were based on "formulae set by federal statute and federal regulations." *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 230 F.R.D. 61, 70 (D. Mass. 2005).

Plaintiffs cite *Conatzer v. American Mercury Ins. Co.*, 15 P.3d 1252 (Okla. Civ. App. 2000) for the proposition that the statutory exemption is limited to "activities that are actively regulated." Pl. Opp. Memo. at 23. *Conatzer* does not say that and, in any event, the case is distinguishable.

The defendant in *Conatzer* was an insurance company that also sold used cars. When sued for its sales practices relating to cars, it claimed an exemption, even though used car sales were not insurance transactions subject to regulation. The court rejected the argument because, as plaintiffs point out, "reselling cars was not an inherit [sic] part of the business of insurance." *Id.* Selling pharmaceuticals is an inherent part of the J&J Defendants' business.

CONCLUSION

The J&J Defendants respectfully request that their motion for summary judgment be granted as to Class 1 and Class 2.

Dated: April 28, 2006

/s/ William F. Cavanaugh, Jr.

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CERTIFICATE OF SERVICE

I certify that on April 28, 2006 a true and correct copy of the foregoing **The Johnson & Johnson Defendants' Reply Memorandum in Support of Their Motion for Summary Judgment as to Class 1 and Class 2** was served on counsel for plaintiffs via Federal Express.

_/s/ Andrew D. Schau_____
Andrew D. Schau